isnar Briefing Paper NO. 44
International Service for National Agricultural Research
October 2000

THE USE OF PROPRIETARY BIOTECHNOLOGY RESEARCH INPUTS AT SELECTED LATIN AMERICAN NAROS

Silvia Salazar, Cesar Falconi, John Komen, and Joel I. Cohen

During the past decade, the world's economy has moved towards becoming more global, and liberalized markets and free trade agreements have been instituted between countries and between trade blocks. With the internationalization of the economy and the advent of free market agreements, the subject of intellectual property rights (IPR) has become an obligatory topic of discussion and negotiation in international trade agreements. Under the changing environment for intellectual property protection, agricultural research organizations need to (1) analyze how new technologies or products can be acquired and under what conditions, and (2) investigate the possibility of research organizations themselves developing means of protection of technologies and products.

The main purpose of this Briefing Paper is to provide an assessment of the use of proprietary biotechnology inputs in the agricultural research systems of selected Latin American countries: Brazil, Chile, Colombia, Costa Rica, and Mexico. A survey was conducted among 13 national agricultural research organizations (NAROs) on the application of proprietary research inputs and prospects for generating innovative products from these. In total, 34 different proprietary technologies and materials and 388 specific applications of these tools were reported.

The main findings of the survey are (1) the NAROs surveyed use proprietary biotechnology inputs extensively, (2) the administrative and academic divisions of the NAROs lack knowledge regarding IPR in agricultural research, (3) there are high expectations for the generation and intellectual property protection of final products from the research done in the NAROs, and (4) in the majority of cases, informal means are used for acquiring proprietary technologies and materials. These findings lead to the following recommendations: (1) a combination of legal, scientific, and technical guidance should be provided to help the NAROs address IPR concerns in a systematic way and in accordance with international policies, (2) specific regulations and policies are needed for the NAROs, and (3) when defining policies and scenarios for the NAROs, it is helpful to distinguish between recommendations for the more academically oriented institutions and those needed for institutions with an applied orientation.

ISSN 1021–2310

Introduction

During the past decade, the world's economy has moved towards becoming more global, with liberalized markets and free trade agreements between countries and between trade blocks. Intellectual property protection originated before these changes. It was implemented by specialists and was of interest primarily to inventors and authors. However, with the internationalization of the economy and the advent of free market agreements, the subject of intellectual property rights (IPR) has become an obligatory topic of discussion and negotiation in international trade agreements.

Because of their opposition to the patent systems in the 1960s, most developing countries with patent laws excluded certain strategic areas such as living organisms (plants and animals) and the essentially biological processes that produce them. This meant the exclusion of many biotechnological inventions. Pharmaceutical and nutritional products were also usually excluded, as well as agrochemical products such as fertilizers, fungicides, herbicides, and insecticides. These are areas of great interest to developed countries and, above all, to the transnational companies that commercialize products in these fields.

The 1991 agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) made it obligatory to patent the inventions of products and processes in all fields of technology for a minimum period of 20 years. While there are some exceptions, such as plants and animals and the essentially biological processes that produce them, this means that other products such as agrochemicals should be subject to patent protection without exception. With regard to biotechnology, innovations arising from microorganisms and microbiological processes are eligible for patent protection under TRIPs. Finally, regarding plant varieties, TRIPs has established protection by means of the patent system or a sui generis system, or a combination of both.

The still increasing adoption of genetic transformation technologies and the gene constructs necessary to carry them out, together with the legal changes taking place in their respective countries, represent great challenges for the national agricultural research systems. For each research organization it is necessary to (1) analyze the opportunities for researchers to acquire new technologies or products and under what conditions and (2) investigate the possibility of research organizations themselves developing means of protection of technologies and products.

The current five-year plan (1998–2002) of ISNAR's Biotechnology Service (IBS) includes research on the effects of IPR on agricultural biotechnology. The goal of this research is to provide information needed to better analyze the options and implications for agricultural research systems in relation to national and international policy decisions regarding IPR, and to understand how IPR affects the dissemination of products to farmers and other end-users. Collecting country-specific data is one way of offering technical assistance to policymakers and research directors, who deal with the implications of IPR developments for their national agricultural research systems.

Purpose and methodology

The purpose of this briefing paper is to assess how proprietary biotechnological inputs are being used in the agricultural research systems of selected Latin American countries: Brazil, Chile, Colombia, Costa Rica, and Mexico. The objective of this analysis is to be able to collaborate with the different countries, especially with their agricultural research systems, in the design of policies and in the decision making regarding IPR, which will help to ensure that international policies are taken into account.

Between July and September 1998, ISNAR conducted a survey among NAROs in the selected countries regarding the application of proprietary research inputs and prospects for generating proprietary products from these inputs. With the assistance of several technical experts, ISNAR constructed a list of the most relevant proprietary technologies and materials. It grouped the technologies and materials into the following eight categories: (1) transformation systems, (2) promoter genes, (3) insect-resistance genes, (4) disease-resistance genes, (5) selectable marker genes, (6) genetic markers, (7) diagnostic probes, and (8) others.

A survey form was developed to determine which proprietary technologies or materials from the categories above are being used at the responding NAROs. Respondents were asked to provide information on specific applications, the means by which intellectual property protection is provided (patents, plant breeders' rights, or other means), and how the center obtained permission for research (e.g., through a material transfer agreement or license). In addition, information was requested on the research products to be derived from the technologies or materials identified, the dissemination of results from this research, and whether any intellectual property protection was to be sought.

A total of 13 organizations (six public universities and seven public research centers) were selected in the five countries. Significant time was taken to provide explanations of the topics covered by the survey. After the survey was completed, more time was taken to address specific results. Each respondent then confirmed the accuracy of the data. The initial findings and recommendations were presented and reviewed in a regional seminar with research managers who had participated in the implementation of the survey. The seminar took place in Costa Rica in September 1999, after which the final report of the study was completed.

As confidentiality was essential for conducting the surveys, the following sections do not contain specific information collected from the NAROs. The focus is on general trends and recommendations are made on the use of proprietary science in the NAROs.

Analysis of data

The Latin American countries selected for the survey have specific legislation covering IPR. Table 1 provides an overview of whether or not it is possible to protect biotechnology products in each of the selected countries and the types of protection that have been granted.

Scientific discoveries are not patentable under the law of any of the selected countries, which is the norm. Chile is the only country where biological processes are patentable. Regarding microorganisms, it is clear that Mexican and Brazilian laws comply with the TRIPs agreement allowing their patent protection. None of the laws consulted were clear regarding the protection of genes. It should be remembered that in dealing with such new matters, terms and conditions have not yet been legally defined and are only just being discussed.

The research organizations responding to the survey currently use proprietary technology as inputs for their biotechnology research. Table 2 shows the use of proprietary technologies by country, which in total accounted for 388 applications of these research inputs. Mexico, Brazil, and Chile emerge as the leading countries using genetic engineering tools in agriculture, whether for experimental purposes or generating a finished product.

Table 3 shows the general use of specific proprietary technologies. The Agrobacterium vector is the most used of all the transformation methods. The high incidence of the use of the promoter CaMV/35S can also be noted. The scant use of genes with very specific characteristics like the Cry genes for insect resistance, together with the wider use of selectable markers such as GUS, and kanamycin and hygromycin resistance genes, show that most of the NAROs consulted are in the initial stages of experimenting in the genetic transformation of plants. This can be affirmed by analyzing figure 3. Here it can be seen that the basic constructs containing selectable markers, promoters, and genetic markers are used more widely in comparison to the products with specific resistance to disease or insects.

Table 1. Opportunities for the Legal Protection of Biotechnological Products in Selected Latin American Countries (1998)

	Discoveries [a]	Biological process	Transgenic plants	Plant varieties [b]	Animal breeds	Micro-organisms	Genes
Brazil	No	(?)	No	Yes	No [c]	Yes	?
Chile	No	Yes	(?)	Yes	No	?	?
Colombia	No	No	Yes	Yes	No	?	?
Costa Rica	No	No	No	No	No	?	?
Mexico	No	No	Yes	Yes	No	Yes	?

No: There is no protection
Yes: There is protection
?: The patentability is not clear in the national regulations.
a: Discoveries (consisting of making known or revealing something that already existed naturally) are not inventions, even though they were previously unknown to mankind.
b: By plant breeders' right following UPOV (International Union for the Protection of New Varieties of Plants) standards.
c: Referring only to animals and not to animal breeds.

Table 2. The Use of Proprietary Technologies and Materials in Selected Latin American Countries (by Reported Number of Applications for Specific Techniques)

Technology Category	Brazil	Chile	Colombia	Costa Rica	Mexico	Total
Selectable markers	37	34	21	8	37	137
Transformation systems	17	21	9	4	15	66
Promoters	10	20	7	4	18	59
Genetic markers	5	39	3	2	6	55
Disease resistance	13	6	2		3	24
Insect resistance	10	1	3		1	15
Diagnostic probes		4	1			5
Others	2	5	3	2	15	27
Total	**94**	**130**	**49**	**20**	**95**	

Table 3. Proprietary Technologies and Materials Covered by Survey

Technology category	Specific tool	No. of applications reported
Selectable markers	GUS	45
(7 tools reported; 137 applications)	Kanamycin	38
	Hygromycin	20
	BAR	15
	HPT	4
	Ac/Ds transposons	3
	Other	12
Transformation systems	Agrobacterium	41
(4 tools reported; 66 applications)	Biolistic	22
	Electroporation	2
	Other	1
Promoters	CaMV/35S	40
(4 tools reported; 59 applications)	Rice actin 1	6
	Maize ubiquitin	5
	Other	8
Genetic markers	RAPD	23
(3 tools reported; 55 applications)	AFLP	16
	Micro-satellite	16
Disease-resistance genes	Coat protein	10
(3 tools reported; 24 applications)	Pathogen derived	4
	Other	10
Insect-resistance genes	Cry genes	7
(3 tools reported; 15 applications)	CpTI	7
	Other	1
Diagnostic probes	Virus probe	3
(3 tools reported; 5 applications)	Golden nematode	1
	RG157	1
Others	Bacterial gene codon	14
(4 tools reported; 27 applications)	Antisense	10
	Cre-lox recombination system	2
	Snowdrop lectin	1
TOTAL		**388**

Figure 1 establishes a relationship between the technologies used by category and the researcher's perception of whether they are protected or not. The figure indicates that for 33% of the applications (129 of a total of 388) of protected technologies, respondents did not know, or had no information regarding the means of protection. This figure can be related to Figure 2, showing a low number of licenses sought by the researchers. These results can be explained by the significant percentage of researchers lacking clear knowledge of which technologies are protected. The survey also showed that most of the researchers consulted were unaware of the principles of territoriality of patents, and, as a consequence, of the implications for the application of their research.

Some of the respondents were aware that a specific tool was protected, or rather that it was patented, but they had not sought the license. One explanation could be the fact that most biotechnology inputs are not patented in their own countries, and therefore the original patent did not seem to be important for them. However, the interviews also indicated that many researchers had no detailed knowledge of the IPR legislation and its implications, and, in addition, that the actual implications depend on the final use of the research results, e.g., a transformed plant. In many cases, the interviews indicated that the respondents did not fully understand the implications of a patent, and what it means in terms of their research work.

Figure 2 shows the methods used by researchers to obtain permission to use proprietary technologies. This figure indicates that 53% of the applications (205 out of a total of 388) of proprietary technology are not covered by a formal contractual arrangement ("lacking written approval", "international collaboration", and "not known"). Furthermore, the use of licenses is low, in contrast to the use of nonwritten agreements and international collaboration. Material transfer agreements (MTA) are extensively used. Most of these agreements restrict the use of research and do not allow the material to be transferred to other colleagues or third parties. The interviews demonstrated that the researchers are unaware of the implications of these restrictions and believe that the MTA will protect them, while in fact a conventional MTA is just a permit for the use of the technology or construct for research purposes only, and may actually prohibit the dissemination to third parties. Most of the responding NAROs are working to produce finished products for use by farmers or other end-users, which means that problems can arise when those products involve the application of proprietary technologies.

Another point to take into account is that even though the technologies or products may not be protected in their countries, if a researcher signs an MTA but fails to comply with the agreement he or she will be in "breach of contract" and subject to civil penalties.

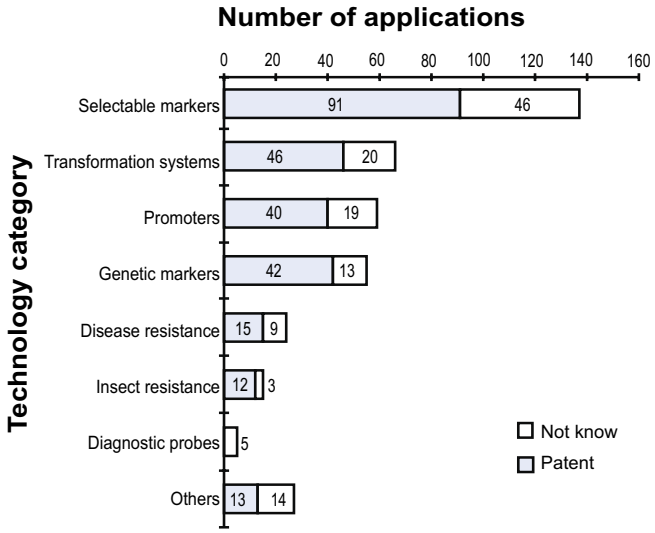

Figure 1. Applications of proprietary technologies and their means of protection (by reported number of applications)

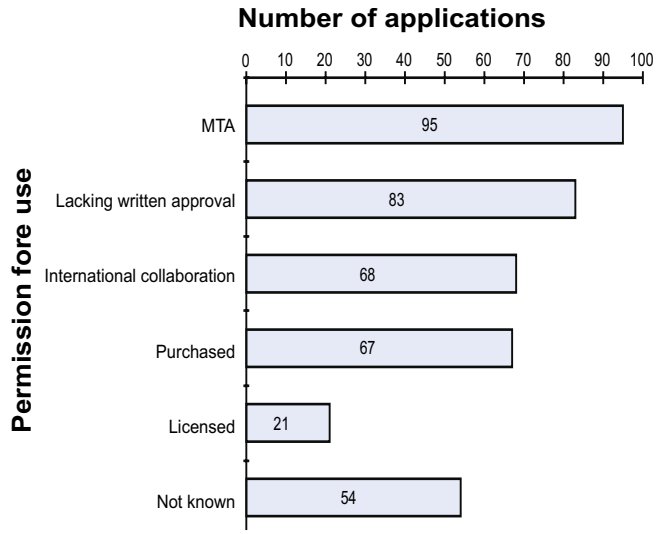

Figure 2. Permission for use of proprietary technologies (by reported number of applications)

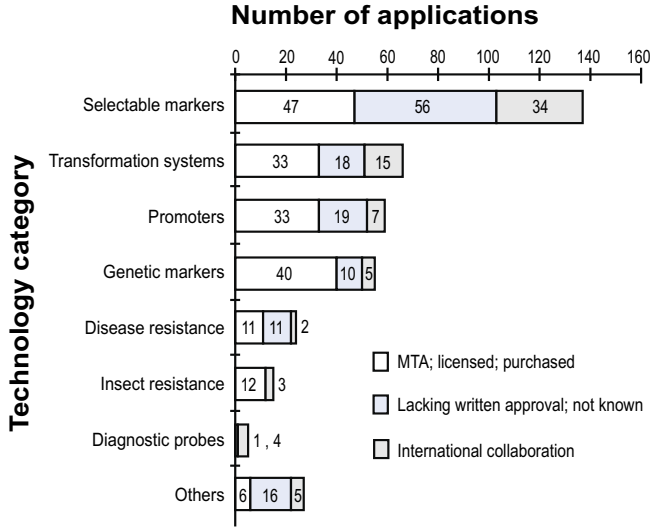

Figure 3. Agreements and potential difficulties in acquiring permission to use proprietary technologies (by number of reported applications)

Figures 2 and 3 show that 18% of the applications of the protected technologies is based on "international collaboration", which includes informal collaborative agreements with international research centers or foreign universities. This could lead to serious complications—in the case of the use of an internationally commercializable product, several entities could demand the rights. This type of collaboration is usually not covered by a formal agreement. And if it is, the agreement probably does not contain clauses that could prevent future claims. Most of these agreements are based on personal contact or on rather general memoranda of understanding between institutions.

The survey results show high expectations among the researchers regarding the NAROs' obtaining intellectual property protection for the results of their research work. The survey identified 50 distinct end products that the respondents expect to generate from their research. Table 4 shows that 74% of the products are expected to be protected, either by patents or by plant variety protection.

Researchers do not seem to be worried about legal difficulties that can arise from their research. Consequently, their research centers have also not fully studied the implications of intellectual property rights for their research. Table 5 shows that the centers do not anticipate problems regarding the dissemination of around 70% of final products derived from their biotechnology research. This minimal concern could be attributed to a lack of understanding of IPR legislation and its implications, the types of crops and technologies used, expectations for local versus export markets, and the emerging status of IPR in each country.

Table 4. Expectations to Protect Products

	Brazil	Chile	Colombia	Costa Rica	Mexico	TOTAL
IPR protection anticipated	11	9	0	0	17	37
No IPR protection	0	3	6	0	0	9
Not known	0	0	2	2	0	4
TOTAL	**11**	**12**	**8**	**2**	**17**	**50**

Table 5. Anticipated Constraints on Dissemination of Products

	Brazil	Chile	Colombia	Costa Rica	Mexico	TOTAL
Constraints anticipated	0	10	6	0	0	16
No constraints anticipated	11	2	2	2	17	34
TOTAL	**11**	**12**	**8**	**2**	**17**	**50**

Emerging policy and management issues

This section is based on the survey analysis above and discusses the emerging policy and management issues related to intellectual property management, coordination, and collaboration.

Different types of research centers have different perceptions of their mission and their role in the field of agricultural biotechnology. Regarding the respondents to the survey, researchers in universities are primarily involved in training, basic research, and acquiring experience in agricultural biotechnological research. As a result, they are not especially concerned about developing final products from their research. In contrast, researchers from the more applied research centers are working on specific application questions and their intention is to achieve final products that can be used in the field. From a policy and intellectual property perspective, it is evident that a greater deal of attention must be given to those centers working on specific applications with a view to producing final products. The use of proprietary technologies exclusively for research purposes does not usually present a great problem, which lessens the concerns of the academic community. However, basic research is not entirely exempt from problems, and the potential difficulties should not be forgotten.

Issues regarding intellectual property management

Policy implications

Overall, the research centers surveyed lack institutional mechanisms to deal with matters related to intellectual property. This was evident with regard to incoming proprietary technologies and products as well as outputs from the research work. The lack of institutional policies and guidelines reinforces the possibility of future legal problems.

Regulations regarding research and use of incoming technologies and products, whether they are proprietary or not, would help clarify issues concerning technology acquisition for scientists. Subsequent policies regarding outputs from the NAROs provided to end-users may also be needed. For example, in most of the centers it is not clear whether inventions carried out in the research center are the property of the center, the provider of the funds, or the researcher.

Human resources and infrastructure

Based on the survey, several observations can be made: (1) of the NAROs selected, none have suitable institutional or legal frameworks to help their scientists with issues regarding IPR and (2) with the exception of two NAROs with very limited capacity, none of the institutions have an office or a person responsible for assisting the researchers on the subject of intellectual property, access to adapted technologies, transfer of technology, or ways to protect their own inventions.

The decision to protect an innovation or not must be an institutional one, based on specific policy and clear guidance. In addition, it must be based on the human resources and the financial capacity of the organization. As the research organizations covered by the survey do not have specific policies and proper resources to manage IPR, while at the same time they expect to seek IPR protection for their research results, it can be concluded that the research organizations underestimate the complexity of IPR management. It is obvious that researchers in the NAROs that are more advanced in the use of proprietary technology know more about intellectual property and the relationship of IPR to laboratory work. However, even in the most sophisticated institutions, there is a general feeling that the researchers do not know about the topic in-depth, and have erroneous opinions about IPR.

Coordination and collaboration

Another important issue in the institutional sphere is the lack of coordination between institutions in the same country, and even between researchers from the same institution. Although the acquisition of technologies and constructs is an institutional issue, it is not treated as such. No one keeps records of contacts, purchases, or signed agreements. The researchers have no institutional support to comply with IPR. Access to materials related to IPR is relegated to the personal capabilities of each researcher and his contacts with colleagues, friends, or professors.

As there is neither collaboration nor monitoring at the institutional level, there is no perception of the potential future problems that may be confronted by the institutions, for instance in collaborative projects. Sometimes institutions work with one, two, or even three other national or foreign institutions on the same project, using inputs, technologies, and gene constructs from each other. In all of these cases there were no signed agreements regulating intellectual property.

Findings and recommendations

The main findings of this study are:

- An extensive use of proprietary biotechnology inputs was found among the NAROs surveyed.
- Limited knowledge was found among administrative and academic/scientific staff of the NAROs regarding IPR in agricultural biotechnology.
- Nevertheless, NAROs have high expectations for the production and intellectual property protection of final products from their research.
- A majority of the applications of proprietary technologies and materials are not covered by formal agreements or licenses.
- A high proportion of the applications of proprietary technologies takes place under informal international collaborations.

These findings lead to the following recommendations:

- A combination of legal, scientific, and technical guidance should be provided to help NAROs address intellectual property rights concerns in a systematic way and in accordance with worldwide circumstances. Such guidance should be provided through collaboration with regional and international expertise.

Specific regulations and policies are needed for the centers in order to:

  - deal with intellectual property issues regarding third-party biotechnological outputs
  - deal with intellectual property issues in regards to products and technologies developed by the NAROs
  - provide guidelines and support to their researchers
  - avoid potential legal conflicts.

- When defining policies and regulations for the NAROs it is helpful to distinguish between those needed for the academically oriented institutions and those needed for the applied technical institutions.

Finally, it should be mentioned that there was a great discrepancy of opinion concerning who has responsibility for ensuring that use of proprietary technologies is clear of legal problems. Of those interviewed, some felt that the responsibility for obtaining permission for use lay with the NARO management, while others said that this was a problem best left to the users of the end product. Implementing the above recommendations will contribute towards a solution not only to this crucial issue, but also to other findings covered in the report.

About the Authors and this Briefing Paper…

Silvia Salazar *is a lawyer specialized in biotechnology and intellectual property rights and works as an ISNAR consultant.* ***Joel I. Cohen*** *is project manager of ISNAR's Biotechnology Service (IBS).* ***Cesar Falconi*** *is a former Research Officer at IBS, and currently with the InterAmerican Development Bank.* ***John Komen*** *is an Associate Research Officer at IBS.* *ISNAR wishes to express its appreciation to the individual NAROs that participated in this study.*

Briefing Papers previously published by ISNAR

No. 43
Biotechnology in African Agricultural Research: Opportunities for Donor Organizations

No. 42
Agricultural Biotechnology Research Capacity in Four Developing Countries

No. 41
Evaluating Research on Natural Resource Management: The Case of Soil Fertility Management in Kenya

No. 40
Benchmark Study. The Agricultural Technology Development Fund for Contract Research: An INIA (Uruguay) Initiative

No. 39
Proprietary Biotechnology Inputs and International Agricultural Research

No. 38
Strategic Decisions for Agricultural Biotechnology: Synthesis of Four Policy Seminars

No. 37S
Estudio de Caso Gerencial Exitoso. La Creacion de Un Sistema Nacional de Investigacion Agricola Coordinado" El Caso de Costa Rica

No. 37
Benchmark Study. The Creation of a Coordinated National Agricultural Research System: The Case of Costa Rica

No. 36
A Social Network Approach to Analyzing Research Systems: A Study of Kenya, Ghana, and Kerala (India)

No. 35
Benchmark Study. A Research Partnership with Farmers: The Case of El Salvador

No. 34
Commodity Program Priority Setting: The Experience of the Kenya Agricultural Research Institute

No. 33
Developing an Integrated Agricultural Research Policy: Experiences from Benin

No. 32
Linkages between Research, Farmers, and Farmers' Organizations in Kenya: A Summary of Findings

No. 31
Linkages between Research and Technology Users in Africa: The Situation and How to Improve It

No. 30
Linkages between Research and Technology Users: Some Issues from Africa

No. 29
Report of a Consultation: Collecting and Managing Environmental Information in Developing Countries

No. 28
Regionalization of Agricultural Research: Selected Issues

No. 27
Colaboración, Gestión y Transferencia de Biotecnología en la Investigación: Cómo Colmar las Necesidades de los Países en Desarrollo

No. 26
Research in an Ecoregional Framework for Sustainable Land Use and Food Production: Report of a Symposium

No. 25
La liaison entre la recherche et les organisations paysannes: le cas de trois pays subsahiens

isnar
Part of the CGIAR Research Network
International Service for National Agricultural Research
Laan van Nieuw Oost Indië 133, 2593 BM The Hague
P.O. Box 93375, 2509 AJ The Hague, The Netherlands
Tel: (31) (70) 349 6100 • Fax: (31) (70) 381 9677
www.cgiar.org/isnar • Email: isnar@cgiar.org